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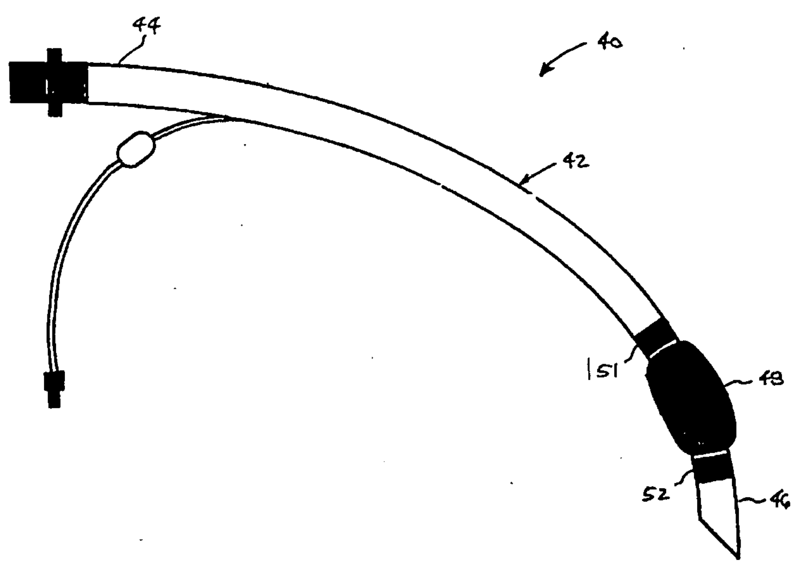
(54) Title: TRACHEOTRODE AND TRACHEAL ELECTROVENTILATION SYSTEM



(57) Abstract: A tracheotrode (40) for electroventilation comprising a tracheal tube (42) having an inflation cuff (48) on its distal end (46) and a bipolar electrode configuration along a surface of the tube including a first electrode (51) proximal to the inflation cuff and a second electrode (52) distal to the inflation cuff. A system and method of electroventilation are also disclosed in which an electrical pulse train is supplied to the electrodes to stimulate inspiration. A cuffless endotracheal tube may be suitable in certain applications, and an embodiment is also contemplated in which a cuff made of conductive elastomer serves as an electrode itself.

WO 01/32249 A1

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TRACHEOTRODE AND TRACHEAL ELECTROVENTILATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

The present application claims the benefit of United States Provisional Application Serial No. 60/163,011, filed on November 1, 1999, and entitled "Tracheal Electroventilation," which application is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

This invention relates to electroventilation, which is the technique of producing inspiration by stimuli applied to inspiratory muscles, directly or though associated nerves, through strategically placed electrodes on or within the body. More particularly, this invention relates to tracheal electroventilation.

It has been known for more than a hundred years that inspiration can be produced electrically. Electrical stimulation of inspiratory nerves and/or muscles provides significant advantages over commonly used ventilators, which force air into a patient's lungs through the nose and/or mouth, intermittently creating a positive intrathoracic pressure in the process. Positive intrathoracic pressure reduced blood flow back to the left heart from the lungs, and thereby decreases cardiac output. In contrast, electroventilation produces inspiration by negative intrathoracic pressure and therefore uses the same mechanism as natural breathing. The method is sometimes called diaphragm pacing, and it is useful in many situations where respiratory support is needed.

To contract the respiratory muscles, most notably including the diaphragm and intercostal muscles, the electrodes are located so that the stimuli are delivered to the appropriate motor nerves. Various electrode sites have been employed, such as at the base of the neck, the anterior axillary and paraxiphoid sites, the seventh intercostal space along the nipple line, over the xiphoid process, and transchest sites. Percutaneous and jugular-vein electrodes have also been used in efforts to obtain

better access to the phrenic nerves, which innervate the diaphragm. One such method, known as intracaval electrophrenic stimulation, involves advancing a bipolar catheter electrode into a jugular vein and applying stimuli that pass through the wall of the vein and reach a phrenic nerve. Another method uses needle electrodes inserted at the cervical motor point. Also, pulsed magnetic fields have been generated with coils placed on or around the neck or on the chest, inducing eddy currents in living tissue to achieve stimulation without the use of conventional conductive skin-surface electrodes. Such methods are described in a paper by L.A. Geddes entitled "Electroventilation – A Missed Opportunity?" and published in the July/August 1998 issue of *Biomedical Instrumentation & Technology.*

It is also known to implant induction coils connected to electrodes around the phrenic nerves in the neck to stimulate inspiration. Such a technique is described in U.S. Patent No. 5,265,604 to Vince and also in a paper entitled "Diaphram Pacing: Present Status" by W. Glenn, published in *PACE*, 1:357-370, 1978.

Esophageal electrodes have also been proposed for electroventilation, as described in U.S. Patent No. 4,960,133 to Hewson and in a paper by D.J. Cochrane et al. entitled "Transesophageal Electroventilation Optimization and Improvement," published in *Chest* in September 1994. The electrodes in the Hewson patent are located in the esophagus beyond the level of the tracheal carina, the ridge at the junction of the main bronchi. The paper by Cochrane et al. indicates placement of an electrode at the gastroesophageal junction and in the stomach, with displacement of the electrode in 2-cm stages in an investigation of esophageal electrode position. The esophageal electrode was used in conjunction with electrodes on the chest.

U.S. Patent No. 5,125,406 to Goldstone et al. describes an electrode endotracheal tube for detecting electromyographic signals in the laryngeal muscles. A pair of electrodes running parallel to the tube axis is provided on the surface of the tube on the proximal side of an inflation cuff, so as to contact the laryngeal muscles when the tube is properly positioned in the trachea. The endotracheal tube is also used for ventilating the lungs during surgery, but its ventilation function does not employ the electrodes and instead is performed in a conventional manner using a respirating machine to supply air through a main ventilation lumen. The patent

teaches that a circumferential electrode configuration could not be used on an endotracheal tube employed for ventilation during surgery.

SUMMARY OF THE INVENTION

The present invention provides a tracheotrode and a tracheal electroventilation system and method. The term "tracheotrode" is a coined term intended to mean a tracheal electrode, preferably in the form of an electrode-bearing tracheal tube.

According to one aspect of the invention, a tracheal electroventilation system comprises a tube sized for insertion in a trachea, the tube having proximal and distal ends and first and second surface electrodes at the distal end, and an electroventilator having first and second outputs connected respectively to the first and second electrodes and operative to supply an electrical pulse train to the electrodes to stimulate inspiration.

According to another aspect of the invention, a tracheal electroventilation system comprises a pair of electrodes adapted to contact an internal tracheal surface, and means for supporting the electrodes in axially spaced relation within a trachea and in contact with an internal tracheal surface at a depth at which one of the electrodes is adjacent to the tracheal carina. The system further comprises an electroventilator having first and second outputs connected, respectively, to the first and second electrodes and operative to supply an electrical pulse train to the electrodes to stimulate inspiration.

A method of tracheal electroventilation is provided as another aspect of the present invention. The method comprises inserting an electrode into the trachea of a patient to a depth at which the electrode is adjacent to the tracheal carina, connecting a second electrode to the patient, either internally or externally, and supplying an electrical pulse train to the electrodes to stimulate inspiration.

A tracheotrode according to another aspect of the present invention comprises a tracheal tube having proximal and distal ends and an inflation cuff on the distal end, and a bipolar electrode configuration on a surface of the tracheal tube, including a first electrode proximal to the inflation cuff and a second electrode distal to the inflation cuff.

A tracheotrode according to yet another aspect of the invention comprises an elongated flexible member adapted for placement in the trachea of a patient without

obstructing the airway, and a conductive inflatable member on the elongated flexible member.

It is a general object of the present invention to provide improvements in electroventilation.

Another object of the invention is to provide effective systems, methods and devices for tracheal electroventilation.

These and other objects and advantages of the present invention will be more apparent upon reading the following detailed description in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a tracheotrode according to one embodiment of the present invention.

FIG. 2 shows a tracheal electroventilation system according to one embodiment of the present invention, along with a corresponding graph of test data.

FIG. 3 is a side view of a tracheotrode according to another embodiment of the present invention.

FIG. 4 shows a tracheal electroventilation system according to another embodiment of the present invention, along with a corresponding graph of test data.

FIG. 5 illustrates a record of data obtained from a dog with a tracheal electroventilation system according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one of ordinary skill in the art to which the invention relates.

A first embodiment of a tracheotrode 10 according to the present invention is shown in FIG. 1, wherein it can be seen that the tracheotrode comprises a tracheal tube 12 having a proximal end 14 and a distal end 16, and an inflation cuff 18 on the distal end approximately 3 cm from the tip 20 of the distal end. The tracheotrode has an electrode 22 distal to the inflation cuff. The electrode may be a ring electrode formed on the exterior surface of the tube with small gage bus wire, e.g., 22 gage solid tinned copper, wrapped around the tube circumference over an axial span of about 1 cm. The electrode is thus approximately 2 cm from tip 20 in the disclosed embodiment. The outer diameter of the tube is approximately 15 mm, although it varies with the size of the patient. The tube is in other respects a conventional tracheal tube, including an inflation port 24 and associated conduit extending through a pilot balloon 26 to cuff 18 in a known manner. Alternatively, the tracheal tube may be uncuffed in certain applications. The tube is suitably of a length adequate to reach the tracheal carina and leave only a small portion of the proximal end out of the patient's mouth in order to minimize dead space in the tube.

Alternatively, an electrode may be formed on an inflatable cuff or balloon made of conductive material, e.g., a conductive elastomer such as rubber or silastic. The conductive cuff may be partially or entirely conductive, and in the former case may have multiple electrodes formed thereon, e.g., one electrode on the proximal end of the cuff and one electrode on the distal end. Alternatively, two conductive cuffs axially spaced from each other on a tube may serve as electrodes in a bipolar

configuration, described below. A single cuff electrode is useful with a chest electrode in a monopolar system, as will now be described.

The tracheotrode of FIG. 1 is useful in a monopolar tracheal electroventilation system according to the present invention. More specifically, as shown in FIG. 2, electrode 22 is connected to a wire 28 that extends through the lumen in tube 12 (or within the tube wall) to and out of the proximal end 14 thereof, and the connecting wire is in turn connected to an output of an electroventilator 30, abbreviated as "EV" in FIG. 2. Electrode 22 serves as the cathode, while a chest electrode 32 is connected by a corresponding wire 34 to an output of the electroventilator (EV) and serves as the anode. The chest electrode is suitably a metal disk electrode a few centimeters in diameter and may be placed over the suprasternal notch, or elsewhere on the chest. The electroventilator includes a pulse generator designed to generate trains of pulses of predetermined duration at a predetermined pulse rate via an isolated output. For example, the pulse generator may generate 10-µsec pulses at a rate of 25 pulses per second to the electrodes. A short pulse duration minimizes the risk of producing cardiac arrhythmia. The duration of the train, which determines the duration of inspiration, may be 1 second, or longer, and the train rate, i.e., the desired breathing rate, may be a selected rate in the range of 10-30 pulse trains or inspirations per minute. The train rate is desirably set slightly higher than the spontaneous respiration rate in order to capture breathing. To provide a smooth inspiration, the current level is suitably increased exponentially, with an exponential rise time constant of 200 msec, up to the maximum current level.

The above specifications are applicable to adult human subjects among others. Variations in some values corresponding to size differences and other differences among subjects are contemplated, such as for use in small children and in animals. For example, other embodiments may include pulse widths less than 10 µsec and up to 20 µsec, pulse rates in the range of 20-40 pulses per second, and a pulse train duration of 0.5 to 3 or more seconds. Other signal parameters and techniques that may be useful to varying degrees in certain applications are described in the following patent and paper, which are incorporated herein by reference: Patent No. 4,827,935 to Geddes et al; and L.A. Geddes,

"Electroventilation – A Missed Opportunity?", *Biomedical Instrumentation & Technology*, 32:401-414, July/August 1998.

Referring to FIGS. 3 and 4, another embodiment of a tracheotrode 40 according to the present invention comprises a bipolar electrode configuration on the surface of a tracheal tube 42, with a first electrode 51 just proximal to an inflation cuff 48 on the distal end 46 of the tube and a second electrode 52 just distal to the inflation cuff. Both electrodes may be ring electrodes identical in construction to electrode 22 described above with reference to FIG. 1, and, as illustrated schematically in FIG. 4, they are connected by separate wires to respective outputs of an electroventilator 60, which may be identical to electroventilator 30 described above. The connecting wires are preferably both internal to the tube, e.g., within the tube wall, and extend out of the proximal end 44 thereof. Tracheotrode 30 may otherwise be identical to monopolar tracheotrode 10. Electrodes 51 and 52 may serve as the anode and cathode, respectively, in the tracheal electroventilation system.

The tracheotrodes described above were tested in dogs to determine the efficacy of such electrode configurations for electroventilation. Seven dogs ranging in weight from were used as test subjects. Each animal was anesthetized with 30 mg/kg pentobarbital, intubated and placed in dorsal recumbency on a V-shaped board. Spontaneous respiration was monitored by observation of the chest and use of a capnometer (Model 47210A, Hewlett-Packard, Waltham, MA). Blood pressure was recorded with a fluid-filled catheter placed in a femoral artery and connected to a Cobe pressure transducer (Cobe Laboratories, Lakewood, CO). To measure inspired volume, the open proximal end of the cuffed tracheal tube was attached to a spirometer filled with oxygen and containing a carbon-dioxide absorber. An electronic signal corresponding to the volume in the spirometer was recorded on a Physiograph available from Narco Bio-Systems, Houston, Texas. Current was increased incrementally from 0 to 600 mA while inspired volume was recorded. FIG. 5 illustrates a typical record of the ECG, blood pressure, respiration, and the stimulus train envelope. The first spontaneous breath stimulation is indicated in the drawing. It can be appreciated from the record that the volume inspired increases with increasing stimulating current (indicated in mA for each stimulus train). The

application of electroventilation did not interfere with the blood pressure record, due to the short duration of the stimuli (8 μsec). Also, there were no episodes of cardiac arrhythmia and no evidence of vagal stimulation at current levels below the 600 mA required for one tidal volume.

FIG. 2 is the volume versus intensity curve for the seven dogs (showing mean ± standard deviation (SD)) using the monopolar tracheal electrode. The mean spontaneous tidal volume of 252 ± 80 mL is identified by the symbol "Δ" on the ordinate axis. Volume inspired increased, as shown in FIG. 2, approximately linearly from 200 to 400 mA at a rate of 1.25 mL/mA. Above 400 mA, the volume inspired slowly plateaus with increasing current, reaching a maximum of approximately 200 mL of air for a 600 mA stimulating current.

FIG. 4 shows the inspired volume versus current for the bipolar tracheal electrode. From 200 to 300 mA, increasing current had little effect on inspired volume. Between 300 and 550 mA, inspired volume increases approximately linearly with current, at a rate of approximately 150 mL/mA. Inspired volume reached a plateau above 550 mA. A maximum inspired volume of approximately 450 mL was reached at 600 mA. Inspired volumes greater than a single spontaneous tidal volume (252 mL) were attainable above 400 mA.

The monopolar and bipolar tracheal electrodes are effective to varying degrees in stimulating inspiration. One advantage of the bipolar electrode is that it produces less peripheral muscle contraction than the monopolar electrode.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention. For example, a single electrode or multiple electrodes adapted to contact an internal tracheal surface may be supported within the trachea on an elongated flexible member other than a tube. Such a flexible member may have a partially conductive head on the end of a thin semi-rigid shaft, the head designed to maintain contact with the internal surface of the trachea without obstructing the airway. The electrodes may be partial ring electrodes, e.g., semicircular in cross-section, and, in addition to being axially spaced from each

other, may be located on the same side or opposite sides of the axis. Also, the ring electrodes may be solid rings rather than wound wire in certain applications.

WE CLAIM:

1. A tracheal electroventilation system, comprising:

a tube sized for insertion in a trachea, said tube having proximal and distal ends and first and second surface electrodes at said distal end; and

an electroventilator having first and second output terminals connected respectively to said first and second electrodes and operative to supply an electrical pulse train to said electrodes to stimulate inspiration.

2. The system of claim 1, wherein said electrodes are ring electrodes.

3. The system of claim 2, further comprising an inflation cuff, wherein one of said electrodes is distal to said cuff and the other of said electrodes is proximal to said cuff.

4. The system of claim 3, wherein said electrodes each comprise small gage wire wrapped around said tube and have an axial length of approximately 1 cm on said tube surface.

5. The system of claim 4, wherein said electroventilator supplies a pulse train of controlled duration, said pulse train comprising pulses less than 20 microseconds in duration.

6. The system of claim 5, wherein said electroventilator supplies pulse trains at a rate of 10-30 trains per minute.

7. The system of claim 6, wherein said electroventilator supplies each pulse train at a current level which increases exponentially with a rise time constant of approximately 200 milliseconds, and wherein the maximum current level is approximately 600 mA.

8. The system of claim 1, wherein at least one of said electrodes is an inflatable member.

9. A tracheal electroventilation system, comprising:

a pair of electrodes adapted to contact an internal tracheal surface;

means for supporting said electrodes in axially spaced relation within a trachea and in contact with an internal tracheal surface at a depth at which one of said electrodes is proximal to the tracheal carina; and

an electroventilator having first and second output terminals connected respectively to said first and second electrodes and operative to supply an electrical pulse train to said electrodes to stimulate inspiration.

10. The system of claim 9, wherein said electrodes are ring electrodes.

11. The system of claim 10, further comprising an inflation cuff, wherein one of said electrodes is distal to said cuff and the other of said electrodes is proximal to said cuff.

12. The system of claim 11, wherein said electrodes each comprise small gage wire wrapped around said tube and have an axial length of approximately 1 cm on said tube surface.

13. The system of claim 12, wherein said electroventilator supplies a pulse train of controlled duration, said pulse train comprising pulses less than 20 microseconds in duration.

14. The system of claim 13, wherein said electroventilator supplies pulse trains at a rate of 10-30 trains per minute.

15. The system of claim 14, wherein said electroventilator supplies each pulse train at a current level which increases exponentially with a rise time constant of

approximately 200 milliseconds, and wherein the maximum current level is approximately 600 mA.

16. The system of claim 9, wherein at least one of said electrodes is an inflatable member.

17. A method of tracheal electroventilation, comprising:

inserting an electrode into the trachea of a patient to a depth at which said electrode is proximal to the tracheal carina;

connecting a second electrode to the patient; and

supplying an electrical pulse train to said electrodes to stimulate inspiration.

18. The method of claim 17, wherein said electrodes are mounted on the distal end of a tracheal tube.

19. The method of claim 17, wherein said second electrode is mounted on the patient's chest.

20. The method of claim 18, wherein said electrodes are ring electrodes.

21. The method of claim 20, wherein said tracheal tube includes an inflation cuff, and wherein one of said electrodes is distal to said cuff and the other of said electrodes is proximal to said cuff.

22. The method of claim 21, wherein said electrodes each comprise small gage wire wrapped around said tube and have an axial length of approximately 1 cm on said tube surface.

23. The method of claim 22, wherein said supplying step includes supplying a pulse train of controlled duration, said pulse train comprising pulses less than 20 microseconds in duration.

24. The method of claim 23, wherein said pulse trains are supplied at a rate of 10-30 trains per minute.

25. The method of claim 24, wherein each said pulse train is supplied at a current level which increases exponentially with a rise time constant of 200 milliseconds, and wherein the maximum current level is approximately 600 mA.

26. The method of claim 17, wherein said electrode inserted into the trachea is formed on a conductive inflatable member.

27. A tracheotrode for electroventilation, comprising:

a tracheal tube having proximal and distal ends and an inflation cuff on said distal end; and

a bipolar electrode configuration on a surface of said tracheal tube including a first electrode proximal to said inflation cuff and a second electrode distal to said inflation cuff.

28. The tracheotrode of claim 27, wherein said first and second electrodes are ring electrodes.

29. The tracheotrode of claim 28, wherein said electrodes comprise small gage wire wrapped around said tube.

30. The tracheotrode of claim 29, wherein each said electrode has an axial length of approximately 1 cm on said tube surface.

31. A tracheotrode for electroventilation, comprising:

an elongated flexible member adapted for placement in the trachea of a patient without obstructing the airway; and

a conductive inflatable member on said elongated flexible member.

32. The method of claim 31, wherein said elongated flexible member is sized to extend from a point just proximal to the tracheal carina to the patient's mouth and a relatively short distance external thereto to minimize dead space.

33. The method of claim 32, wherein said elongated flexible member has a shaft substantially narrower in cross-section than the patient's trachea.

34. The method of claim 31, wherein said elongated flexible member is a tube.

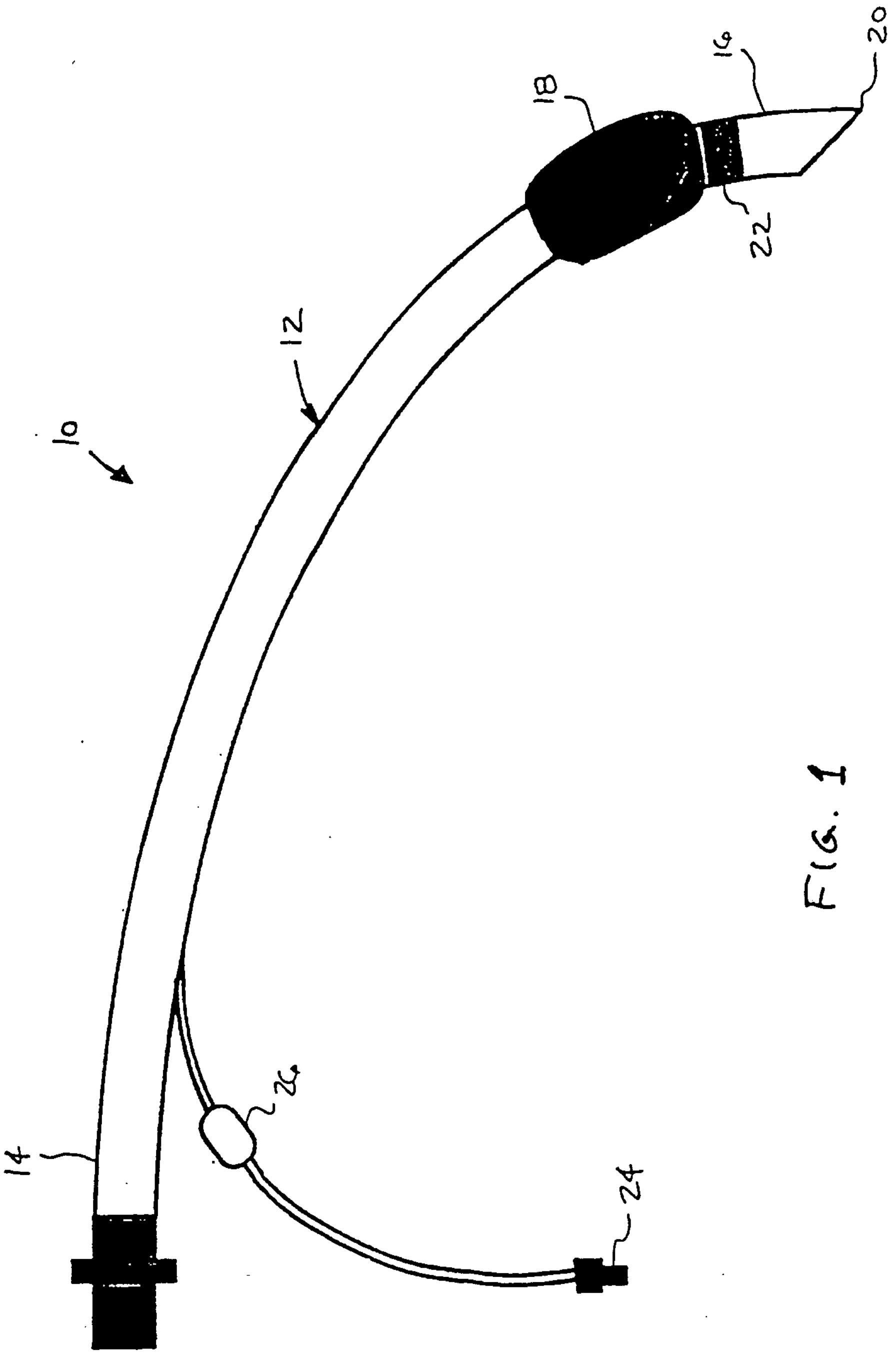
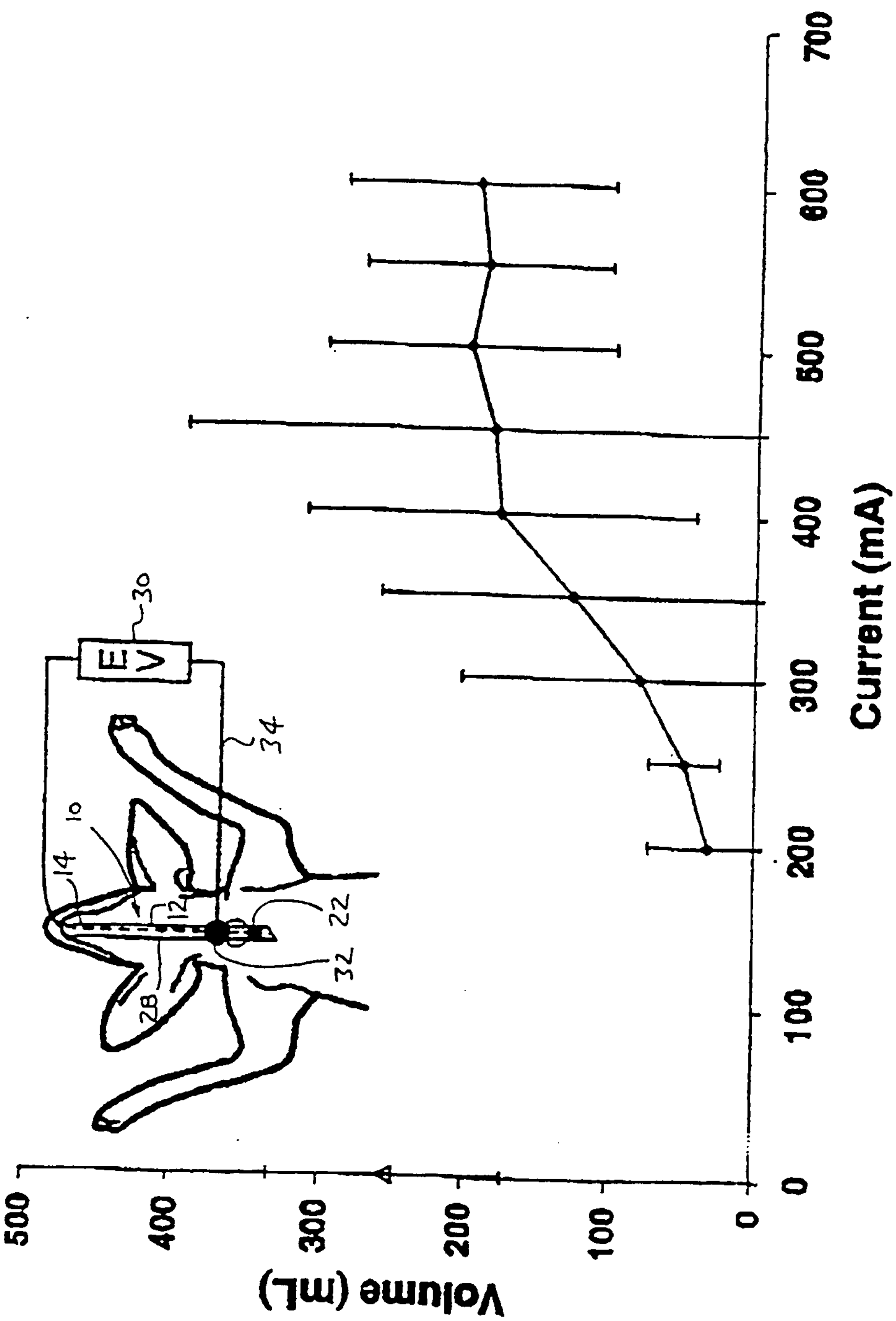


FIG. 1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100
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300
400
500
Current (mA)
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200
300
400
500
600
700
E
V
30
34
10
14
12
22
28
32

FIG. 2

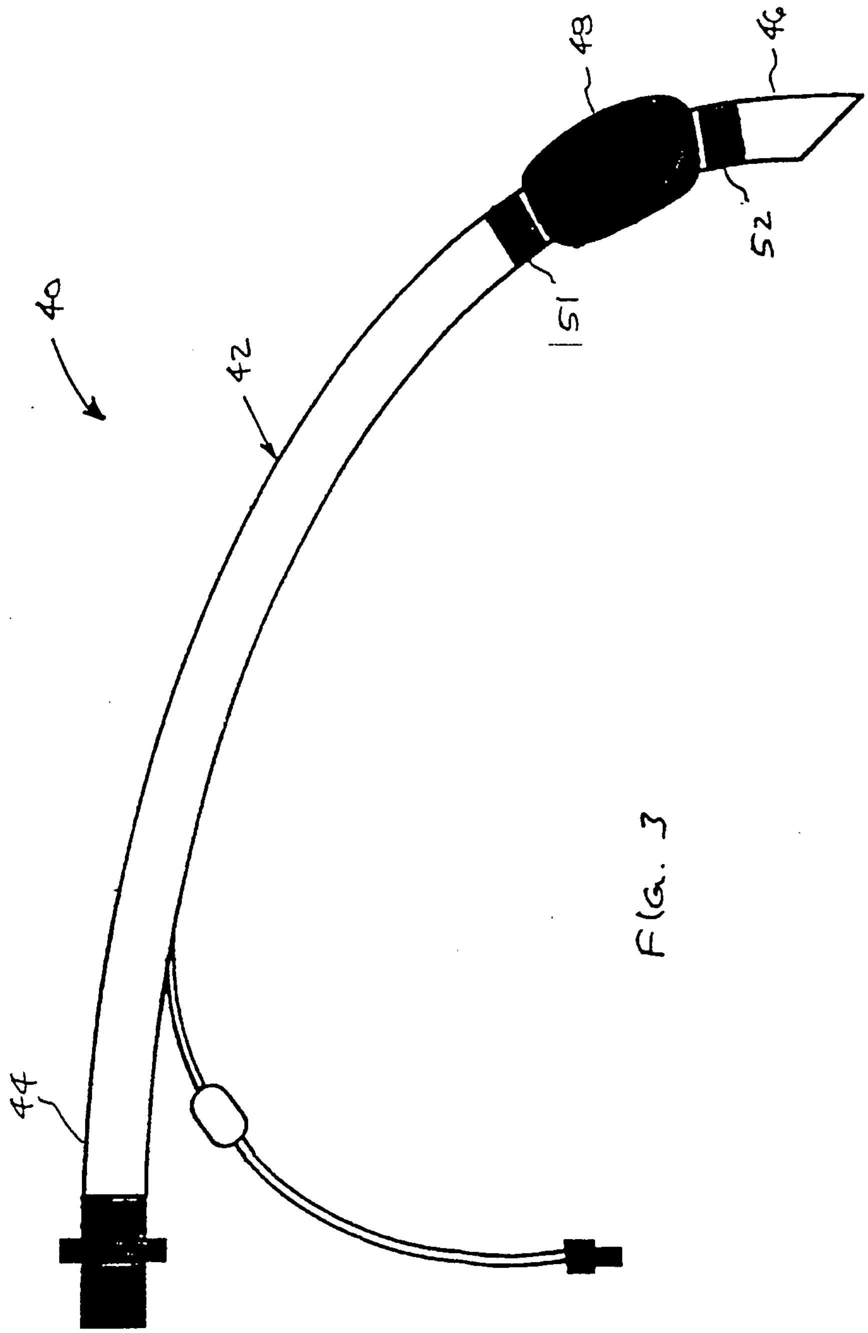
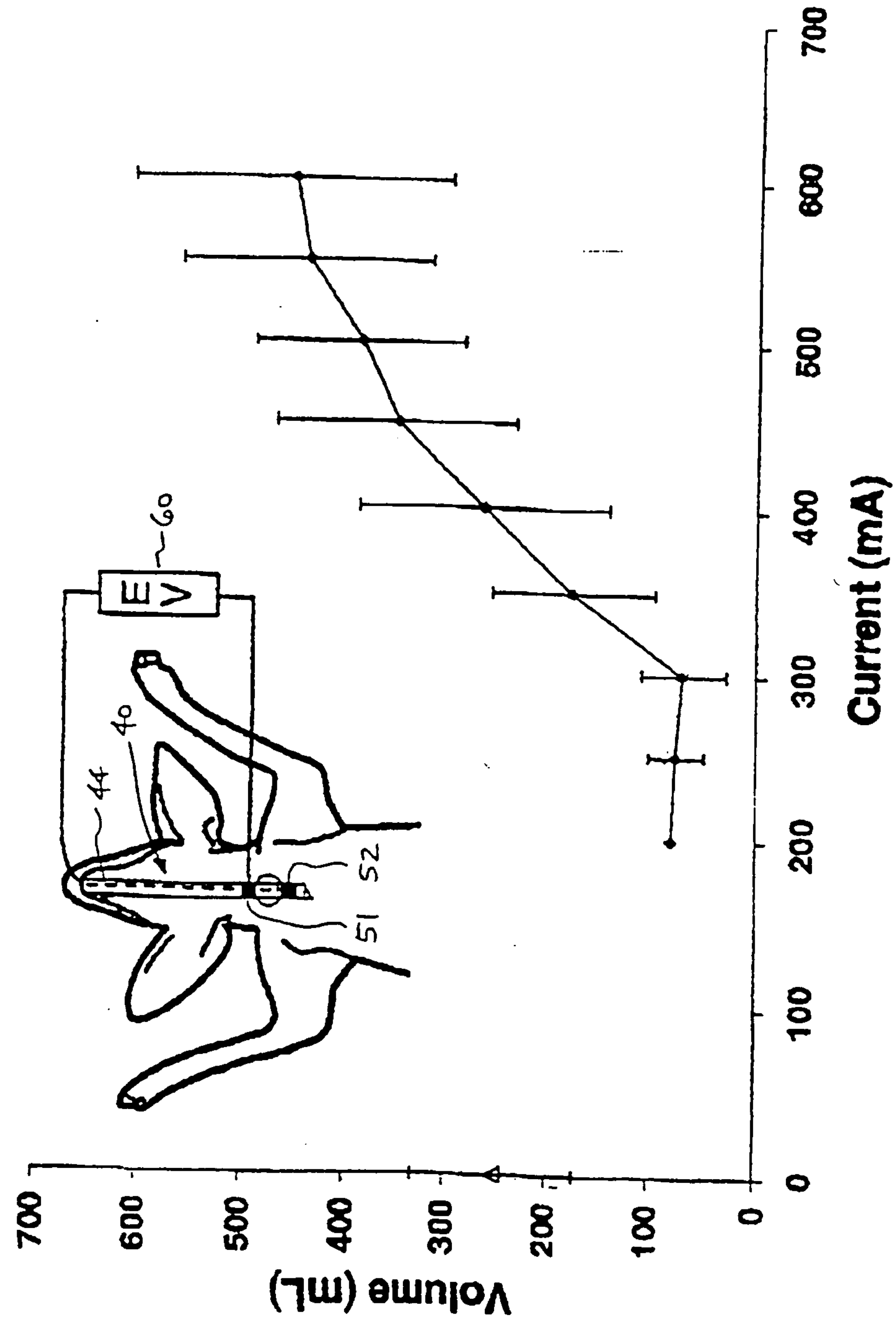


FIG. 3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400
300
200
100
0
Current (mA)
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100
200
300
400
500
600
700
E
V
60
44
40
51
52

FIG. 4

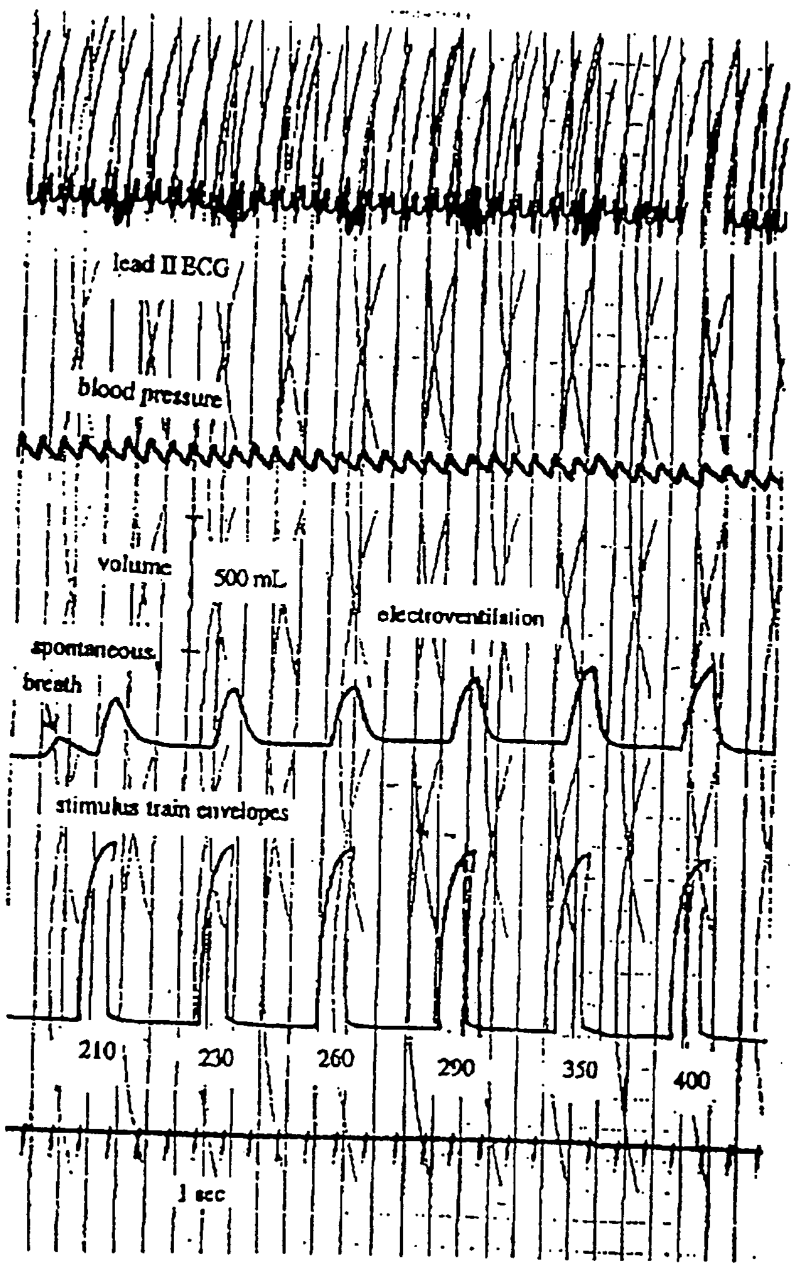
lead II ECG
blood pressure
volume
500 mL
electroventilation
spontaneous breath
stimulus train envelopes
210
230
260
290
350
400
1 sec

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/41748

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A 61 M 16/00; A 62 B 7/00, 9/06; F 16 K 31/02; A 61 B 5/04
US CL :128/204.18, 204.21, 207.14; 600/380; 607/124

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.18, 204.21, 207.14, 207.15, 207.16, 207.17; 600/380, 393; 607/124

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST electroventilation, tracheal, endotracheal, tube eletrodes, sensors

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4827935 A (Geddes et al) 9 May 1989, Electroventilation	1-34
Y	US 5678535 A (DiMarco) 21 October 1997, Electroventilation	1-34
Y	US 5911218 A (DiMarco) 15 June 1999, Electroventilation	1-34
Y	US 4960133 A (Hewson) 2 October 1990, Tracheal interface to affect electroventilation	1-34
Y	US 5125406 A (Goldstone et al) 30 June 1992, Tracheal interface capable of affecting electroventilation	1-34

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 FEBRUARY 2001	10 APR 2001

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INTERNATIONAL SEARCH REPORT
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International application No.
PCT/US00/41748

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5584290 (Brain) 17 December 1997, Tracheal interface affecting electroventilation	1-34
Y	US 5024228 (Goldstone et al.) 18 June 1991, Tracehal interface capable of affecting electroventilation	1-34